

John Hellerstedt, M.D. Commissioner

Laboratory Clinical Specimen Collection and Storage Guidance for Lung Injury Associated with E-Cigarettes, or Vaping

The purpose of this document is to provide sample collection and storage guidance for clinicians in the care of patients who meet the probable or confirmed case definitions for lung injury associated with e-cigarettes, or vaping. CDC recommends that clinicians consult their local or state health department for the department's recommendations on collection and storage of clinical samples. This document supplements CDC's guidance by providing specific information for reporting in Texas.

Prior to submitting samples, complete this form

(https://www.dshs.state.tx.us/tobacco/pdf/TX-Vaping-Case-Report-Form.pdf) and call 512-422-0925 to discuss sample submission, then follow directions to submit the form to the DSHS Environmental Surveillance and Toxicology Branch. DSHS will confirm that the samples are eligible to be submitted the state public health laboratory and will provide State Case ID numbers and further instructions.

SPECIMEN TYPES

CDC has indicated clinical specimens (e.g., plasma/serum, urine, bronchoalveolar lavage (BAL)) could be used for investigative testing. At this time, CDC is prioritizing BAL fluid for testing. Plasma/serum and urine samples will only be accepted in conjunction with BAL samples from the same patient. See below for detailed guidance for collection, handling, and shipping of these samples. **PLEASE NOTE:** If specimens are tested by CDC, CDC will report results to the Texas Department of State Health Services (DSHS) and results will then be forwarded to the submitter.

SPECIMEN COLLECTION AND HANDLING

Specimen Collection Time Point

 Clinical specimens (urine and plasma) are to be collected ONLY at the time when BAL fluid is to be collected or upon Patient Admission to Hospital

Specimen Labeling and Handling

• All specimens must be labeled with at least two patient specific identifiers, but must include: the *State Case ID number* and the patient's *medical record number*.

- The identifiers <u>must appear</u> on all primary containers and the associated submission form.
- A manifest with the CDC Case ID, State Case ID, Patient Medical Record number, specimen type, and collection date must be included with the shipment.
- Specimens must be labeled as to type (e.g. serum, urine, etc.).

Bronchoalveolar lavage fluid (BAL fluid) samples

- Due to the invasive nature of BAL sampling, the decision and timing for a patient to undergo BAL should be left to the judgement of the treating clinicians.
- Optimal timing: These specimens may be obtained at any time during the clinical course but may be most informative if obtained prior to initiation of antimicrobial or steroid therapy. If antibiotics or steroids have been initiated, course and duration should be noted on the back of the G-2A form.
- Specimen collection: Collect specimens in sterile containers. BAL fluid should undergo culture and routine centrifugation followed by cellular analyses and cytopathology, including lipid and other staining, as clinically indicated at the local institution.

Guidance for retaining BAL fluid samples left over from routine clinical evaluation:

BAL Fluid for Further Cytopathologic Evaluation

- Remaining uncentrifuged BAL fluid and supernatant from centrifuged BAL fluid should be labeled as such and be retained.
- Up to 10 unstained cytology slides prepared from the cell pellet should be briefly fixed in formalin and retained for future evaluation.
- Excess cell pellet after cytopathologic evaluation can be divided in half, with half being fixed in formalin and stored at room temperature for further cytopathologic evaluation. The other half should be set aside for Chemical or Lipid Analysis (see below)

BAL Fluid Submission for Chemical or Lipid Analysis

- Place remaining uncentrifuged fluid and centrifuged supernatant from centrifuged fluid into sterile vials with external caps and internal O-ring seals. If there is no internal O-ring seal, then seal tightly with the available cap and secure with Parafilm®.
- Label each specimen container with the patient's medical record number, state
 case ID number, the specimen type, subsection of lung lavaged, and the date the
 specimen was collected.
- FREEZE the BAL Fluid Sample for Chemical or Lipid Analysis at freezer temperatures of -20 °C or lower and store frozen.
- SEE BELOW FOR SHIPPING INSTRUCTIONS.

Plasma Samples

- For each patient, collect up to 8 mL of blood in two (2) 4-mL PURPLE-top (K2 -EDTA) plastic tubes. (Note: <u>DO NOT</u> use gel separators.)
- Mix contents of tubes by inverting them 8 -10 times.
- Label tubes in order of collection. Example: #1, #2.
- Centrifuge blood tubes for 15 minutes at 1000 to 1300 g-force to separate the
 plasma from whole blood cells within 6 hours of collection. Check with the centrifuge
 rotor manual (or RCF to RPM table) for the proper RPM (e.g. 2400 RPM) to use with
 your specific rotor.
- Aliquot plasma into cryotubes with corresponding collection sequence number (e.g. #1, #2)
- Label each specimen container with the patient's medical record number, state case ID number, the specimen type, and the date the specimen was collected.
- FREEZE these specimens at freezer temperatures of -20 °C or lower and store frozen.
- SEE BELOW FOR SHIPPING INSTRUCTIONS.

Urine Samples

- For each patient, collect approximately 40 mL to 60 mL of urine in a screw-cap urine cup without preservative.
- Transfer 8 mL to 10 mL of urine to a urine collection tube(s) with no preservative. (Example: BD 364991 Vacutainer® Urinalysis Transfer Straw Kit: 8.0 mL, 16 x 100 mm Plus Plastic Conical Tube, without preservative, or similar)
- Indicate on the tube how the sample was collected if the method was other than "clean catch" (example: catheterization).
- Label each specimen container with the patient's medical record number, state case ID number, the specimen type, and the date the specimen was collected.
- FREEZE these specimens at freezer temperatures of -20 °C or lower and store frozen.
- SEE BELOW FOR SHIPPING INSTRUCTIONS.

SPECIMEN SHIPPING

- Specimens should be shipped in a biohazard bag and stored on enough dry ice to keep specimens frozen. Please only ship the same specimen types together in a box (e.g., BAL fluids only in one box, plasma tubes only in one box, etc.)
- Do not ship on Fridays or before government holidays. Ship specimens Monday-Thursday by overnight delivery.
- Complete a DSHS G-2A Serology Specimen Submission Form (September 2017 revision):
 - A separate G-2A is required for each specimen (plasma, urine, etc.) submitted
 - A submitter ID is required to submit specimens. To request a submitter ID, please complete the Submitter Identification (ID) Number Request Form

available at www.dshs.texas.gov/lab/MRS_forms.shtm#Microbiological and follow the instructions for submitting the form. Please include an email address in section 3 of the Submitter ID Request Form for a faster response.

Tips for completing G2-A form:

- ✓ Section 2 Patient Information: Place patient's State Case ID number in the "Last Name" field, leave "First Name" field blank, and place patient's medical record # in the "Medical Record #" field; complete date of collection field
- ✓ Section 3 Specimen Source or Type: check the "Other" box and write in specimen type
- ✓ Section 9 CDC Reference Tests: check the "Other" box and write in Vaping
- Ship to the physical address: TX DSHS Lab Services, ATTN: Walter Douglass 512-776-7569, 1100 W. 49th Street, Austin TX, 78756
- Record the shipping tracking number and notify your local health department that a specimen is being shipped.